



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/531,747

04/18/2005

Peggy E. Hellberg

2395 US F

3474

7590

08/06/2008

Alcon Research
6201 South Freeway
Fort Worth, TX 76134

EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,747	HELLBERG, PEGGY E.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/2007, 7/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of glaucoma in the reply filed on June 30, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Application

2. Applicant has glaucoma for the examination.

Due to restriction, based on election of glaucoma, claim 3 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-2 and 4 are present for examination at this time.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-2 and 4 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to the use of any histone deacetylase inhibitor for the treatment of any “acute or chronic degenerative condition or disease of the eye”. The method requires treatment of unspecified disease and no evidence indicates that all possible diseases were known to the applicant. The method also requires the use of any number of histone deacetylase inhibitors where the specification does not indicate that all possible histone deacetylase inhibitors were known to the applicant.

First, the claims and description define the histone deacetylase inhibitors by what it *does* and not what it *is*. Second, it describes the histone deacetylase inhibitors through a measurement of action on histone deacetylase with no disclosure as to requisite determinations such as the degree of inhibition. This does not adequately describe which histone deacetylase inhibitors are addressed as it is inadequate to describe a product to be administered through the function of another mechanism, which can be affected by many conditions like temperature (e.g. fever) not related to the invention. Thereby it also does not describe the use of all histone deacetylase inhibitors for glaucoma much less any “acute or chronic degenerative condition or disease of the eye”. As a result, the fact pattern indicates that the artisan was not in possession of the claimed method of use.

5. Claims 1-2 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

The claims are drawn to a method of treating a degenerative condition of the eye using a histone deacetylase inhibitor.

2) The state of the prior art:

The prior art does not recognize that the treatment of all degenerative conditions of the eye is accomplished easily, and does not recognize that one type of treatment or one group of compounds can be effective for all ocular degenerative disorders as some disorders cannot be treated such as hereditary optic neuropathies (see Merck Manual sheets). The prior art (Danziger et al.) also acknowledges that there is a structure function relationship and that compounds that do not have the same structure (i.e. all histone deacetylase inhibitors) are not likely to share the same function (i.e. treatment of glaucoma).

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are very broad and encompass the use of any histone deacetylase inhibitor for the treatment of any degenerative condition of the eye. The dependent claims are also very broad and encompass the use of any histone deacetylase inhibitor for the treatment of glaucoma.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the treatment of a few degenerative conditions of the eye using a few histone deacetylase inhibitors. However, the specification provides no guidance, to enable one of ordinary skilled in the art to use the invention commensurate in scope with the claims. In *re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: " It is well settled that in cases involving chemical and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired results". Applicant's specification does not set forth a representative number of examples of histone deacetylase inhibitors and degenerative conditions of the eye.

7) The presence or absence of working examples:

The applicant's specification is drawn to the use of one histone deacetylase inhibitor for the treatment of certain ocular degenerative disorders no clinical examples, examples of topical formulations, and disclosure of one topical regime for treatment.

8) The quantity of experimentation necessary:

Since compound structure and activity for each pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine all histone deacetylase inhibitors which are capable of treating glaucoma as well as all ocular degenerative disorders.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by Pang et al. (U.S. Pat. 5681854).

Pang et al. teaches the use of valproic acid (a known histone deacetylase inhibitor-see Phiel et al.) for several ophthalmic disorders including glaucoma (Abstract, Col. 1 line 1-10, Col.2 line 3-27, Col. 3 line 1-Col. 4 line 50, Claim 1-3).

Art Unit: 1612

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Xiao (U.S. Pat. 7250514).

Xiao teaches the use of particular histone deacetylase inhibitors for several conditions including neovascular glaucoma (Abstract, Col. 14, line 8-Col. 15 line13, Col. 29 lines 49-61, Col. 30 line 19).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Double Patenting

10. Claims 1-2 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 4-5 of copending Application No. 10/694309 (U.S. Pat. Publication 20040092431). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are to specific histone deacetylase inhibitors for degenerative conditions or disease of the eye particularly primary open angle glaucoma which would anticipate the broader claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-2 and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 and 4 of copending Application No. 11/836309 (U.S. Pat. Publication 20080004311). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are to specific histone deacetylase inhibitors for degenerative conditions or disease of the eye particularly glaucoma which would anticipate the broader claims of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. Claims 1-2 and 4 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612